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EXAMINER				
LEWIS, RALPH A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/550,197
Filing Date: September 21, 2005
Appellant(s): SUL, YOUNG-TAEK

Robert Bushnell
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 12, 2010 appealing from the Office
action mailed May 11, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
7, 13, 19

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

NEW GROUND(S) OF REJECTION

Claims 7, 13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

FR 2610512 A	Culleron	8-1988
US 5,588,838	Hansson et al	12-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 7, 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuilleron (FR 2610512 A) in view of Hansson et al (US 5,588,838).

Cuilleron discloses a bone implant having a cylindrical core (Figure 5) with helical threads (2b) for screwing the implant into the intramedullary channel of a prepared femur. Formed on the helical threads 2b is a continuous pattern of microthreadings (2c) that increase the exposed surface area of each helical thread 2b (see Figure 7). Cuilleron also shows that implant threads can include inclined flanks have a continuum of micro-patterns thereon as shown illustrated in Figure 4, said micro-patterns as shown having a polygonal cross-section. The micro threads (1c) shown in Figure 4 comprise a series of recesses and protrusions incised thereon which form the aforementioned micro-patterns (i.e. triangular shaped patterns 1f, also representative of ridges). Furthermore, Figure 4 also shows that each screw thread comprises crests (i.e. the free distal end of each thread) and roots (i.e. proximal base portion of each thread). The flanks (i.e. inclined sides of each thread) connect the crests with the roots. Lastly, because the polygonal cross-section of the micro-patterns can be triangular, Figure 4 demonstrates how their polygonal outline can appear open at one side (i.e. between crests of adjacent triangles) when viewed on a cross-sectional plane. Cuilleron further discloses that the micro-patterns located on the threadings can have a profile other than a triangular profile (i.e. see attached EPO automated translation, page 3, lines 1-3). Cuilleron does not explicitly disclose that said micro-

patterns have “continuous and repeated arcuate cross-sectional outlines” as required by the claims.

Hansson et al teach a bone implant that has continuous micro threads 9 (Figure 1) or alternatively microthreads formed by a continuous microbeads (Figure 3) (note column 3, lines 11-21). The microbeads have an arcuate design, wherein the spaces between each bead are identical grooves (i.e. microbeads; column 2, lines 34-37). In view of the Hansson et al alternative teaching, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use arcuate shaped micro-patterns in the threads of Cuilleron in order to avoid, or at least minimize, stress-concentrations in the bone tissue around said microthreads as taught by Hansson et al. Furthermore, the examiner notes that such an arcuate shape helps to avoid, or at least minimize, additional cutting into the bone of the patient during insertion, such that the patterns can be relied on instead for providing a region for bone-implant integration to occur.

Additionally, Cuilleron fails to disclose a specific distance between each micro-pattern leaving the determination to the ordinarily skilled artisan desiring to practice the invention. Hansson et al, however, teach that the distance between adjacent threads may be approximately 0.2 mm (200 μ m) (column 2, line 28) which helps to provide for rapid bone growth into the microthreads (column 2, lines 53-59). Merely providing for similar such spacing (e.g. 150 μ m) for the undisclosed spacing of the Cuilleron microthreads in order to promote rapid bone growth into the microthreading would have been obvious to one of ordinary skill in the art.

With regard to the difference between the claimed 150 μ m spacing and the Hansson et al taught 200 μ m spacing, the examiner is of the position that 200 μ m meets the claimed “on an

order of 150 μm " and "approximately 150 μm ." The originally filed specification provides no specific definitions for interpreting the "on the order of"/"approximately" modifying language; accordingly the examiner is required to give the terminology its broadest reasonable interpretation. In this particular case, the examiner finds the interpretation that 200 μm is "on the order of" and "approximately" 150 μm to be reasonable, particularly in view of the specification which indicates that "the pattern may have any size in the range of several dozens of μm or several hundred of μm " (written description page 5, lines 18 and 19). Alternatively, the examiner is of the second position, that if 200 μm is found not to meet the claimed "on an order of 150 μm " and "approximately 150 μm " limitations, then one of ordinary skill in the art would have found it obvious as a matter of routine skill in the art to have merely tested different micro pattern spacings in the Cuilleron bone implant in order to determine the claimed optimal or workable values specifically claimed by applicant based on the teachings of Hansson et al. to use a distance allowing for rapid bone growth. It is noted that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable values involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

NEW GROUND(S) OF REJECTION

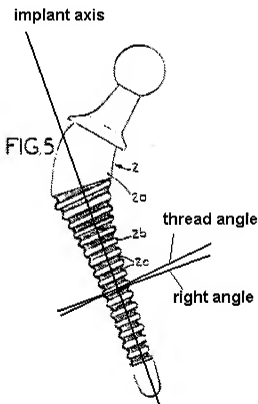
Claims 7, 13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The originally filed specification fails to reasonably describe the claimed subject matter in a manner sufficient to convey to one skilled in the art that applicant had possession of the invention defined by the limitations in claims 7 and 13 that “said recesses being separated by a distance on an order of 150 μm ” and in claim 19 the limitation that “the distance between the neighboring micro-patterns being approximately 150 μm .” More particularly, the originally filed specification (page 5, lines 15-25) gives the specific example of 150 μm , but fails to reasonably convey the “on an order of” or the “approximately” limitations that were added during prosecution to modify the “150 μm ” limitation.

(10) Response to Argument

First, appellant argues that the base reference to Cuilleron fails to teach the claimed limitation of “helical threads”, but rather only discloses “spaced-apart concentric rings.” The examiner simply disagrees. The supplied machine translation of the Cuilleron reference repeatedly states that the implant has “threading” (translation page 1, line 14; page 2, lines 1 and 28; page 3, line 5) and is “screwed in” (translation page 1, lines 1-2, 6 and 9; page 2, line 17; page 3, line 20). Moreover the drawings illustrate spiral threading as illustrated below in the examiner annotation of Figure 5. In light of the disclosure referring to the implant being “threaded” and being “screwed in,” as well as, the Figures which illustrate angled threads, one of ordinary skill in the art would reasonably interpret the reference as teaching “helical threads” as required by the present claims.



Second, appellant argues that the use of the Hansson et al reference to teach the use of helical threads for modification of the Cuilleron reference having concentric circumferential rings is not obvious because it would prevent Cuilleron from being used for its intended purpose. Initially, it is noted that the examiner has not argued for such a modification of the Cuilleron reference because the Cuilleron reasonably discloses helical threads as set forth above. However, even if it were interpreted that Cuilleron only reasonably teaches concentric rings, then the examiner is of the position that the use of conventional helical threading in the Cuilleron implant such as that disclosed Hansson et al would have been obvious to the ordinarily skilled artisan so that one could have “screwed in” the implant into bone tissues as required by the Cuilleron disclosure. Applicant’s argument that concentric rings somehow would prevent

counter-clockwise rotation in the Cuilleron implant whereas spiral threading would not be logical or persuasive. A spiral threading would provide a resistance to rotation as it is tightened in to place and the threads are loaded with compression forces from the bone.

Third, appellant argues that the threads 9 of Hansson et al do not include the required continuum of micro patterns. The examiner agrees. Applicant misrepresents the rejection of record. Cuilleron is the reference relied upon for teaching helical threads having micro patterns on the flanks thereof.

Fourth, appellant argues that the applied references fail to teach the limitations in claims 7 and 13 that “said recesses being separated by a distance on an order of 150 μm ” and in claim 19 the limitation that “the distance between the neighboring micro-patterns being approximately 150 μm .” The examiner disagrees. As specified above in the rejection the examiner is of the position that (1) the Hansson et al teaching of 200 μm spacing meets the broadly claimed “on an order of 150 μm ” and “approximately 150 μm ” or alternatively, (2) the Hansson et al disclosure to space the micro-patterns at a distance to allow rapid bone growth and teaching that a 200 μm spacing provides an appropriate distance would allow one of ordinary skill in the art to arrive at the claimed “approximately 150 μm ” through the routine optimization of the variable parameter.

In the response of October 23, 2008 a declaration under 37 CFR 1.132 by the inventor concluded that the “150 μm micro-pattern provide optimal site for bone ingrowth” (paragraph 11) and provides evidence in the form of test results that show the ingrowth of bone into micro-patterns of 150 μm . The examiner notes, however, that the claims are not being limited to 150 μm , but rather “on an order of 150 μm ” and “approximately 150 μm .” The declaration is not commensurate with what is being claimed. Moreover, the declaration fails to provide results for

any other spacings and as such fails to provide any basis for arguments that the results are “optimal”, unexpected or have any meaningful distinction over the similarly sized spacing of Hansson which is disclosed as promoting bone growth. Moreover, the mere testing of similarly sized spacings in order to find the most optimal spacing is of no patentable merit, but rather the result of routine testing obvious to the ordinarily skilled artisan.

One desiring to practice the Cuilleron invention would have to determine the spacing of the microthreads 2c on their own accord since Cuilleron is silent on the issue. Hansson et al teach that for similar microthreads in a bone implant a spacing of around 200 μm is desirable because it provides for rapid bone growth. Merely, selecting similar spacing for the Cuilleron microthreading would have been obvious to the ordinarily skilled artisan in view of the Hansson et al teaching.

Finally, appellant’s quotation of Thomas Edison that “Genius is one percent inspiration, ninety-nine percent perspiration” while perhaps inspiring, has little to do with the statutory requirements for protecting intellectual property. The Supreme Court rejected the “sweat of the brow” doctrine even for the minimal originality requirement in copyrights. *See Feist Publications v. Rural Telephone Co.*, 499 U.S. 340 (1991).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Ralph A. Lewis/
Primary Examiner, Art Unit 3732

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD T HAJEC/

Director, Technology Center 3700

Conferees:

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732

/Janet C. Baxter/
TC 3700 TQAS